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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,295	03/22/2004	Paulo LaColla	11874-076-999	1837
20583	7550	04/02/2008		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			04/02/2008 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/806,295

**Applicant(s)**

LACOLLA ET AL

**Examiner**

LEONARD M. WILLIAMS

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/01/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-9, 12-13, 25-26, 19-24, 27- 46 and 49-65 is/are pending in the application.

4a) Of the above claim(s) 8, 9, 12, 13, 25 and 26 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 19-24, 27- 46 and 49-65 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Detailed Action

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/01/2007 has been entered.

***Response to Amendment***

The amendment received 11/01/2007 amending claims 19, 20, 23-24, 27-28, 30-36, 40 and 42-43 to recite that in the compounds recited at least two of R4', R5', R6', and R7' are not hydrogen has been entered.

The amendments to the claims are sufficient to overcome the 103(a) rejections of the last office action. The examiner has examined the claims and specification thoroughly and has deemed that a new rejection based on written description needs to be made.

The applicant's refer to their being 64 claims when in fact there is a pending claim 65. The rejections reflect such.

***Response to Arguments***

Applicant's arguments with respect to claim 19-24, 27-46 and 49-65 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24, 27- 46 and 49-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the current claims are drawn to methods for the treatment of an HIV-infection in a host comprising administering an effective of a compound of formula (I). The claims lack description of how to use the compounds in methods for treatment of an HIV-infection in a host by administering a compound of formula (I). The specification only describes the binding of a small number of compounds (in Table 1) to Glycoprotein or human serum albumin (in comparison with the prototype compounds efavirenz and nevirapine). Table 2 discloses a small number of compounds where R is 3,5 diMe and R1 is a mono substituted amide (or in one embodiment an  $\alpha,\beta$ -unsaturated ketone-see compound 6), wherein in vitro cell based activity in WT and drug resistant cell lines is described. Table 3 discloses a

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small number of compounds wherein R is either H or 3,5 diMe and R1 is either 5,6-Cl, 5,7-Cl, 4,5-F, 5,6-F and 5,7-F in the same assays as Table 2. In all the disclosed embodiments in Tables 1-3 only the sulfate linkage (Y of formula I) is disclosed. As such applicants do not have sufficient written description of all embodiments of formula (I) in a method for the treatment of an HIV-infection in a host as claimed. The only sufficiently described embodiments of formula (I) in said methods are those described in Tables 1-3.

### ***Conclusion***

No claims are allowed.

Claim 57 appears free of the art and would be allowable if written in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEONARD M. WILLIAMS whose telephone number is (571)272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617